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TITLE: Method for diagnosis of helicobacter pylori infection

PUBLICATION-DATE: April 22, 2004

INVENTOR-INFORMATION:

NAME	CITY	STATE	COUNTRY	RULE-47
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Putnam, David L.	Sammamish	WA	US	

ASSIGNEE-INFORMATION:

NAME	CITY	STATE	COUNTRY	TYPE CODE
Photonic BioSystems, Inc.				02

APPL-NO: 10/ 294352 [PALM]
DATE FILED: November 13, 2002

RELATED-US-APPL-DATA:
Application is a non-provisional-of-provisional application 60/331275, filed November 13, 2001,

INT-CL: [07] A61 B 5/08, G01 N 33/497, G01 N 31/00

US-CL-PUBLISHED: 600/532; 073/023.3, 422/084
US-CL-CURRENT: 600/532; 422/84, 73/23.3

REPRESENTATIVE-FIGURES: 1B

ABSTRACT:

A rapid, non-invasive breath-test method and device for diagnosing the presence or absence of H. pylori in a subject without administration of isotopic tracers is described. The device consists of a highly sensitive colorimetric ammonia sensor placed in contact with sampled subject breath. The sensor is measured using appropriate reflection spectroscopy instrumentation. The breath-test method consists of measuring a basal ammonia level with the device, administering non-isotopic urea and continuing measurement of the ammonia content in a plurality of consecutive breaths. Diagnostic differences in breath ammonia are identified between H. pylori infected and uninfected individuals.

RELATED APPLICATIONS

[0001] This application claims the benefit of the filing of U.S. Ser. No. 60/331,275 entitled "Method for Diagnosis of Helicobacter Pylori Infection" filed

on Nov. 13, 2001, hereby incorporated by reference.

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☐	L5	(pylori or helicobacter or pylroi or pylrois or pyloris or pylorum or pyloridis or hpylori)	6774
☐	L6	(stool or faecal or fecal or feces or faeces or excrement or (colonic near3 (contents or excreta or material)))	49714
☐	L7	L6 same l5	162
☐	L8	L7 not l1	151
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Terms	Documents
L8 same (hybridoma or monoclonal or mono-clonal or moab or mab or m-ab or mo-ab or antibodies or antibody)	50

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L10: Entry 50 of 50 File: DWPI Feb 9, 2004

DERWENT-ACC-NO: 1995-224441
DERWENT-WEEK: 200413

TITLE: Chromatographic device for specific binding assay - uses a barrier, having an an aperture, to control delivery of sample and reagent, provides improved accuracy and precision

Basic Abstract Text (2):
USE - The device is used to perform immunoassays, opt. with signal amplification, e.g. for detection of lipopolysaccharides, haemoglobin (in faeces), antibodies to Helicobacter pylori etc.. More generally any other specific binding assays (e.g. lectin or receptor plus ligand; enzyme plus inhibitor or substrate, complementary nucleic acids) can be done.

First Hit Fwd Refs

L10: Entry 25 of 50 File: USPT Aug 22, 2000

DOCUMENT-IDENTIFIER: US 6107464 A
TITLE: iceA gene and related methods

Detailed Description Text (46):
The sample can be a fluid sample comprising any body fluid which would contain IceA, a H. pylori cell containing the antigen or an antibody against H. pylori, such such as blood, plasma, serum, saliva, gastric juice, sputum, mucus, urine and stool. Tissue samples can include gastric or duodenal tissue.

First Hit Fwd Refs

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L5: Entry 3 of 3 File: USPT Feb 10, 1998

DOCUMENT-IDENTIFIER: US 5716791 A
TITLE: Immunoassay for H. pylori in fecal specimens

Abstract Text (1):
A process for the determination of H. pylori in a fecal specimen comprising (a) dispersing a fecal specimen suspected of carrying H. pylori in a sample diluent; (b) (b) contacting the fecal specimen in the diluent with a first polyclonal antibody for H. pylori antigen to form a complex of the antibody and the antigen; (c) separating said specimen and said complex; (d) exposing the complex to a second polyclonal antibody for said antigen and a portion of the antibody reacting with said complex, one of said first and second antibody being bound to a solid carrier and the other being labeled with a detection agent; and (e) determining the amount of the labeled antibody and in turn determining the presence of H. pylori antigen in said fecal specimen.

Brief Summary Text (4):
Several major antigens have been identified and used in immunoassays in the detection of H. pylori antibodies. However, these assays have not exhibited the specificity and sensitivity that are desired in serodiagnosis. Newell, D. G., et al. Serodian. Immunother. Infec. Dis.,, 3:1-6 (1989). One problem with of these immunoassays is cross-reactivity. Studies of the dominant antigens in H. pylori, in particular, the putative flagellar protein, which has a molecular weight of 60 Da, have shown that some of these antigen are not specific to H. pylori and also found in other bacteria such as C. jeuni and C. coli. A second problem that has been encountered in designing immunoassays for H. pylori is strain variation. Substantial differences in the antigens has been observed in different strains of H. pylori. These problems preclude designing an assay around the use of a single antigen. They also rule out the use of monoclonal antibodies. One approach that has been taken to improving the specificity and selectivity of antibody immunoassays for H. pylori has been to use a mixture of antigens from different H. pylori strains which mixture is enriched with certain antigen fragments. One ELISA which detects H. pylori antibodies in a blood sera is commercially available from Meridian Diagnostics. This assay uses a bacterial whole cell lysate as the antigen.

CLAIMS:

1. A process for the determination of H. pylori in a fecal specimen which comprises:

(a) dispersing a fecal specimen suspected of carrying H. pylori in a sample diluent; diluent;

(b) contacting the fecal specimen in the diluent with a first polyclonal antibody for H. pylori antigen to form a complex of the antibody and the antigen;

(c) separating said specimen and said complex;

(d) exposing the complex to a second polyclonal antibody for said antigen and a portion of the antibody reacting with said complex, one of said first and second

antibody being bound to a solid carrier and the other being labelled with a detection agent; and

(e) determining the amount of the labelled antibody and in turn determining the presence of H. pylori antigen in said fecal specimen.

5. The process of claim 1 wherein said polyclonal antibody is obtained by sensitizing an antibody-producing mammal with H. pylori cells.

6. The process of claim 4 wherein the sample diluent contains a protein selected from the group consisting of fecal bovine serum, normal goat serum, guinea pig serum, horse serum, casein, albumin, gelatin, and bovine serum albumin.

8. The process of claim 5 wherein the cells are cells from a plurality of H. pylori strains.

12. A process for the determination of H. pylori in a fecal specimen which comprises:

(a) dispersing a fecal specimen suspected of carrying H. pylori in a sample diluent; diluent;

(b) contacting the fecal specimen in the diluent with a first polyclonal antibody for H. pylori antigen bound to a solid carrier and a second labelled polyclonal antibody for H. pylori to form a complex of the antibodies and the antigen;

(c) separating said specimen and said complex;

(d) determining the amount of the labelled antibody and in turn determining the presence of H. pylori antigen in said fecal specimen.

13. A process for the determination of H. pylori in a fecal specimen which comprises:

(a) dispersing a fecal specimen suspected of carrying H. pylori in a sample diluent; diluent;

(b) contacting the fecal specimen in the diluent with a first polyclonal antibody for H. pylori antigen produced by a first antibody-producing species and bound to a solid carrier to form a complex of the antibody and the antigen;

(c) separating said specimen and said complex;

(d) contacting the antibody-antigen complex formed in step (b) with a primary polyclonal antibody for H. pylori antigen obtained from a second antibody-producing species to produce a antibody-antigen-antibody complex;

(e) removing the primary antibody not present in the complex from step (d);

(f) contacting the antibody-antigen-antibody complex formed in step (d) with a secondary antibody, said secondary antibody being an antibody for the second antibody-producing species, whereby said secondary antibody forms a complex with said antibody-antigen-antibody complex; and

(g) determining the presence of H. pylori antigen in said fecal specimen.

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Search Results - Record(s) 2 through 50 of 50 returned.

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(19) BUNDESREPUBLIK DEUTSCHLAND

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Die folgenden Angaben sind den vom Anmelder eingereichten Unterlagen entnommen

(54) Verfahren zum Nachweis von Helicobacter pylori in Stuhl- und Speichelproben

(57) Verfahren und Testsystem zum Nachweis von Helicobacter und/oder Camphylobacter in Stuhl-, Speichel- und Sekretproben durch einen Doppelantikörper-Sandwich-Bindungsassay, wobei mindestens zwei verschiedene Primärantikörper eingesetzt werden, von denen der erste Helicobacter- oder Camphylobacter-Antigen erkennt und der zweite menschliches Immunglobulin-A, bevorzugt sekretorisches Human-IgA und Human-IgA2. Der Sekundärantikörper ist martiert, bspw. mit Biotin, Fluorescein, alkalischer Phosphatase oder Meerrettichperoxidase. Der erste Primärantikörper ist bevorzugt eine Mischung verschiedener polytonaler Antikörper gegen unterschiedliche Helicobacter pylori-Stämme.

DE 100 06 432 A 1

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(54) Title: METHOD FOR DETECTING *HELICOBACTER PYLORI* AND *HEILMANII* IN FECAL AND SALIVARY SPECIMEN AND BIOPSY MATERIAL

(54) Bezeichnung: VERFAHREN ZUM NACHWEIS VON HELICOBACTER PYLORI UND HEILMANII IN STUHL- UND SPEICHELPROBEN UND BIOPSIEMATERIAL

(57) Abstract: The invention relates to a method for detecting pathogenic organisms, especially *Helicobacter pylori* and *H. heilmanii*, in fecal, salivary and secretion specimen by a double antibody sandwich assay. The inventive method is characterized by dissolving or dispersing the specimen together with a pathogenic antigen in a buffer solution and contacting the buffer solution with a solid phase to which at least two primary antibodies are bound, one of which specifically binds to the pathogenic antigen and the other to human immunoglobulin A, washing the solid phase of non-specifically bound proteins and contacting the solid phase with a secondary antibody that specifically binds to the pathogenic antigen; and determining the amount of specifically bound secondary antibody.

(57) Zusammenfassung: Verfahren zum Nachweis von krankheitserregenden Organismen, insbesondere Helicobacter pylori und H. heilmanii, in Stuhl-, Speichel- und Sekretproben durch einen Doppelantikörper-Sandwich-Bindungsassay, gekennzeichnet durch Aufnehmen oder Dispergieren der Probe mit Erregerantigen in einer Pufferlösung und Zusammenbringen der Pufferlösung mit einer festen Phase, an der mindestens zwei primäre Antikörper gebunden sind, von denen einer Erregerantigen und der andere menschliches Immunglobulin-A spezifisch bindet; Waschen der festen Phase von nicht spezifisch gebundenen Proteinen und Zusammenbringen der festen Phase mit einem sekundären Antikörper, der spezifisch an Erregerantigen bindet, und Bestimmen der Menge an spezifisch gebundenem Sekundärantikörper.

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(81) 指定国 (国内): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

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(54) Title: IMMUNOCHROMATOGRAPHIC TEST PIECE AND DIAGNOSIS KIT

(54) 発明の名称: イムノクロマトグラフィー試験片および診断キット

(57) Abstract: It is intended to provide an immunochromatographic test piece and a diagnosis kit whereby infection with *Helicobacter pylori* can be judged at a high sensitivity with the use of feces as specimens. An immunochromatographic test piece comprising a laminate composed of a rectangular antibody immobilized substrate which has, on its bottom end, a support holding a colored latex labeled-material and a liquid sample-absorbing support made of filter paper laminated thereon in the order from the bottom to the top, and on its top end, a water-absorbing support made of filter paper laminated thereon. In the antibody immobilized substrate, a monoclonal antibody undergoing an antigen-antibody reaction with native catalase of *H. pylori* is immobilized on a nitrocellulose sheet. In the support holding the colored latex particle labeled-material, nonwoven fabric is impregnated with a colored latex particle-labeled anti-*H. pylori* antibody wherein a monoclonal antibody undergoing an antigen-antibody reaction with native catalase of *H. pylori* is immobilized on colored latex particles.

[続葉有]

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Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

WO 03/093818 A2

(54) Title: METHOD FOR PRE-TREATING STOOL SAMPLES

(54) Bezeichnung: VERFAHREN ZUR VORBEHANDLUNG VON STUHLPROBEN

(57) Abstract: The invention relates to a method for pre-treating stool samples, whereby Helicobacter pylori antigens are separated from bonds comprising endogenous antibodies. Said pre-treatment is carried out before the assay of Helicobacter pylori antigens in the stool, using immunological techniques.

(57) Zusammenfassung: Die Erfindung betrifft ein Verfahren zur Vorbehandlung von Stuhlproben, um H.pylori-Antigene aus Bindungen mit endogenen Antikörpern abzuspalten, wobei besagte Vorbehandlung vor der Untersuchung auf H.pylori-Antigene im Stuhl mittels immunologischer Techniken durchgeführt wird.

First Hit Fwd Refs

L10: Entry 35 of 50 File: USPT Nov 17, 1998

DOCUMENT-IDENTIFIER: US 5837240 A
TITLE: Multimeric, recombinant urease vaccine

Drawing Description Text (8):
FIGS. 5A, 5B and 5C are graphs showing the bacterial score versus the levels of serum IgA, serum IgG, and fecal IgA antibodies from mice immunized with recombinant H. pylori urease and cholera toxin (CT).

Drawing Description Text (9):
FIGS. 6A, 6B, 6C and 6D are graphs showing the bacterial score versus the levels of serum IgA, serum IgG, and fecal IgA antibodies from mice immunized with recombinant H. pylori urease and enterotoxigenic E. coli heat-labile toxin.

Detailed Description Text (56):
The effect of immunization route upon the anti-urease antibody response was examined in mice. Swiss-Webster m ice were immunized four times at ten day intervals with either: 1) 200 .mu.g recombinant purified H. pylori urease with 10 .mu.g CT, either with or without NaHCO.sub.3, by oral administration; 2) 200 .mu.g recombinant purified H. pylori urease and 10 .mu.g CT with NaHCO.sub.3, by by intragastric administration; or 3) 10 .mu.g recombinant purified H. pylori urease with Freund's adjuvant by subcutaneous administration. One week after the fourth vaccine dose, mucosal and serum antibody responses were examined by ELISA using microtiter plates coated with 0.5 .mu.g of native H. pylori urease. Serum samples were diluted 1:100 and assayed for urease-specific IgA and IgG. Fresh fecal pellets, extracted with a protease inhibitor buffer (PBS containing 5% non-fat dry milk, 0.2 .mu.g AEBSF, 1 .mu.g aprotinin per ml, and 10 .mu.M leupeptin), were examined for fecal anti-urease IgA antibody. In some experiments, fecal antibody values were normalized for total IgA content determined by ELISA, with urease-specific fecal IgA expressed in A.sub.405 units/mg total IgA in each sample. Saliva samples were collected after stimulation with pilocarpine under ketamine anesthesia, and tested for urease-specific IgA at a dilution of 1:5.

Detailed Description Text (97):
The role of anti-urease antibodies in Helicobacter therapy, i.e., the clearance of H. felis from infected mice, was examined by first infecting Balb/c mice with 10.sup.7 H. felis. Four weeks after infection, the mice were orally immunized with 200 .mu.g recombinant urease plus 10 .mu.g CT. Control mice were given 10 .mu.g CT only. Antigen was administered 4 times at one week intervals. Animals were sacrificed 4 and 10 weeks after the last immunization, and serum and fecal samples were collected for ELISA.

First Hit

L10: Entry 41 of 50 File: JPAB Nov 22, 2002

DOCUMENT-IDENTIFIER: JP 2002333447 A
TITLE: INSPECTION METHOD FOR DETERMINING INFECTION TO HELICOBACTER PYLORI

Abstract Text (2):
SOLUTION: The inspection method comprises determining the infection to Helicobacter pylori by detecting the native catalase of Helicobacter pylori present in an alimentary canal excrement with a monoclonal antibody for the native catalase of Helicobacter pylori. The monoclonal antibody is the one produced by hybridoma 31A3 (FERM P-18329) and/or hybridoma 82A3 (FERM P-18328).

WEST Search History

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☐	L2	L1 and (pylori or helicobacter or pyloris or pyloridis or pylro or pyloris or hpylori or h-pylori or pylorum).ti,ab,clm.	8
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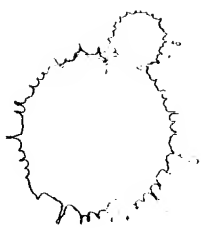

gelatin (jel′ă-tin)

A derived protein formed from the collagen of tissues by boiling in water; it swells up when put in cold water, but dissolves only in hot water; used as a hemostat, plasma substitute, and protein food adjunct in malnutrition.

[L. *gelo,* pp. *gelatus,* to freeze, congeal]

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Terms	Documents
L2 and (pylori or helicobacter or pylroi or pylrois or pyloris or	12

pylorum or pyloridis or hpylori)	

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L3: Entry 11 of 12 File: DWPI Feb 16, 1999

DERWENT-ACC-NO: 1999-166634
DERWENT-WEEK: 199938

TITLE: A process for detecting the presence of Helicobacter pylori in faecal samples samples - which comprises collecting a smear of a faeces on a substrate and contacting the smear with polyclonal antibodies

INVENTOR: KOZAK, K J; LARKA, C V ; YI, C S A

PRIORITY-DATA: 1997US-0897732 (July 21, 1997), 1996US-0647115 (May 9, 1996)

Search Selected Search ALL Clear

PATENT-FAMILY:

	PUB-NO	PUB-DATE	LANGUAGE	PAGES	MAIN-IPC
☐	US 5871942 A	February 16, 1999		007	G01N033/554

INT-CL (IPC): G01 N 33/554; G01 N 33/569

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Terms	Documents
L8 same (hybridoma or monoclonal or mono-clonal or moab or mab or m-ab or mo-ab or antibodies or antibody)	50

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Terms	Documents
L8 same (hybridoma or monoclonal or mono-clonal or moab or mab or m-ab or mo-ab or antibodies or antibody)	50

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